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09/856,182	09/05/2001	Galip Akay	P6671OUS0	3068

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/856182

Applicant(s)

Atay

Examiner

1/10/03

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Pri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 7/31/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 62-101 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 62-101 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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Claims in the application are 62-101, which are all claims in the application.

In a response of 7/31/03 to a restriction requirement of 12/4/02, applicants canceled claims 1-61 and added new claims 62-101, and  
5 elected claims 62-74 drawn to Group II with traverse.

Applicants traverse the restriction requirement on the ground that the claims of Groups I, III and IV require the process of Group II. On reconsideration and in view of the new claims, the restriction requirement is with drawn.

10 It is noted that claim 75 is dependent on canceled claim 61 and dependent claim 94 is dependent on canceled claim 26. In view of the statement in the traverse that Groups I, III and IV require the process of Group II, it is presumed these are typographical errors and the claims are intended to be dependent on claim 62.

15 ***Specification***

The disclosure is objected to because of the following informalities: the specification fails to contain headings designating different sections.

20 The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

25 The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- 30 (a) Title of the Invention.  
(b) Cross-Reference to Related Applications.

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(c) Statement Regarding Federally Sponsored Research or Development.

(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).

(e) Background of the Invention.

1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(i) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

The following suggestions are made.

Page 1,

above line 4 insert --

BACKGROUND OF THE INVENTION

1. Field of the Invention

--.

Between lines 17 and 19 insert --

2. Description of the Related Art

--.

Page 4, between lines 12 and 14 insert --

SUMMARY OF THE INVENTION

--.

Page 8, between lines 17 and 19 insert --

BRIEF DESCRIPTION OF THE DRAWINGS

(Insert a brief description of each drawing)

DETAILED DESCRIPTION OF THE INVENTION

--.

Appropriate correction is required.

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***Claim Objections***

Claims 75-101 are objected to because of the following informalities: the claims are dependent on canceled claims.

5 Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 62-101 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was  
20 filed, had possession of the claimed invention.

The conditions of claim 62 in the last paragraph of the claim at the top of page 2 of the amendment of different pore sizes provided by different conditions are not readily apparent in the specification. The pages and lines of the specification where these pore sizes and  
25 conditions are recited should be pointed out.

The conditions of dependent claims 64-74, 76-93 and 95-101 are not readily apparent in the specification. The page and lines should be pointed out where the conditions of each claim are recited.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claim 62 in the last paragraph of the claim at the top of page 2 of the amendment requiring six different alternative processes requiring different steps and conditions to obtain different pore sizes.

The claims are further confusing and unclear by claim 62 failing to set forth clear, distinct and positive process steps. It is further unclear how the process in the first paragraph of the claim on page 1 of the amendment is modified by each of the six different process conditions recited in the last paragraph of the claim at the top of claim 2 since the modifications required at the top of page 2 are vague and general.

Terms such as "high internal phase emulsion", "approaching", "predominantly extensional", and "type" where recited in the claims are uncertain as to meaning and scope.

Dependent claim 63 is unclear as to how it further limits claim 62 since claim 63 repeats most of what is already in claim 62. Similarly,

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dependent claims 64-69 and 72-74 are unclear where in the process of claim 62 the conditions of the claims are inserted into the process of claim 62.

Claim 75 is unclear how the process of claim 62 can produce the polymer scaffold of claim 75 since claim 62 does not have conditions to provide antecedent basis for a scaffold as required by claim 75.

Claim 75 is further unclear by failing to provide sufficient description of polymer structure to be clear as to structure required. It is uncertain as to how one would know when discrete zones are present since the zones are not described sufficiently to know what constitutes a zone. It is uncertain to what constitutes an internal phase of the polymer, and how the pores and interconnects relate to each other and form polymer structure.

Claims 76-93 are unclear as to how the conditions of the claims further modify the structure of the polymer required by claim 75.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

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owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention  
5 was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 62-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hough et al (5,071,747) in view of Shively et al (WO  
10 97/32612) (both listed on form 1449).

The claims are drawn to making a microcellular polyhipe polymer scaffold by polymerizing a high internal phase emulsion of an immiscible dispersed phase in a continuous phase. Also claimed is the resultant scaffold and a system containing the scaffold and cells.

15 Hough et al disclose a process of making a scaffold as a support for cells by polymerizing monomers or prepolymers in a continuous phase of an emulsion to obtain a scaffold having pores and interconnections.

Shively et al disclose obtaining heterogeneous foams by polymerizing a high internal phase water-in-oil emulsion (HIPE).

20 It would have been obvious to use polymerizing a high internal phase water-in-oil emulsion (HIPE) in Hough et al to obtain the result of a heterogeneous foam as disclosed by Shively et al since this foam has an advantage as disclosed by Shively et al of having different regions with different properties or functions, and it would have been  
25 expected that such a foam would be advantageous in Hough et al as a



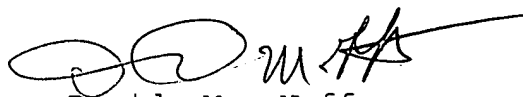
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cell scaffold. The conditions of dependent claims for polymerizing would have been obvious from conditions disclosed by Hough et al and Shively et al. The scaffold of Hough et al is used as a support for cells, and combining the scaffold with cells as in claims 94-101 would have been obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN

10/20/03